# **Program Announcement**

#### for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

# **Ovarian Cancer Research Program**

## **Pilot Award**

Funding Opportunity Number: W81XWH-13-OCRP-PA Catalog of Federal Domestic Assistance Number: 12.420

## SUBMISSION AND REVIEW DATES AND TIMES

• **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 12, 2013

• **Invitation to Submit an Application:** July 2013

• **Application Submission Deadline:** 11:59 p.m. ET, August 28, 2013

• **Peer Review:** October 2013

• **Programmatic Review:** December 2013

This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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#### I. FUNDING OPPORTUNITY DESCRIPTION

## A. Program Description

Applications to the Fiscal Year 2013 (FY13) Ovarian Cancer Research Program (OCRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). Appropriations for the OCRP from FY97 through FY12 totaled \$196.45 million (M). The FY13 appropriation is \$20M. The overall goal of the FY13 OCRP is to eliminate ovarian cancer by supporting innovative, high-impact research. The OCRP's long-term priorities are:

- Understand precursor lesion/stem cell, microenvironment, and pathogenesis/ progression of ovarian cancer;
- Improve performance and reliability of disease markers and imaging toward screening and selecting the best therapeutic approaches;
- Address issues in survivorship;
- Enhance pool of ovarian cancer scientists; and
- Investigate tumor response to therapy including tumor survival, dormancy, cell death, clonal evolution, tumor heterogeneity.

#### **B.** Award Information

The OCRP Pilot Award supports conceptually innovative, high-risk/high-reward research that could ultimately lead to critical discoveries or major advancements that will drive the field of ovarian cancer research forward. The proposed research should include a testable hypothesis based on strong scientific rationale and serve as a catalyst to expand or modify current thinking about and/or approaches in ovarian cancer research. *Preliminary data are not required, but are allowed. The strength of the application should be based on sound scientific rationale and logical reasoning. Clinical trials will not be supported by this award mechanism.* 

**OCRP Definition of Innovation** (*UPDATED for FY13*): Innovative ideas for the OCRP are those that, if proven correct, will provide new paradigms, technologies, molecules, or applications that have the potential to prevent ovarian cancer or improve the treatment of individuals with this disease.

Research that represents an incremental advancement on previously published work is not considered innovative. The following list, *although not all-inclusive*, provides examples of research that is *not innovative* and will not be considered for funding under this mechanism:

- Exploring a previously tested hypothesis in a different cell line or in a new population
- Using a published series of in vitro assays to further characterize a model system
- Incorporating known biomarkers into in vivo or clinical models of ovarian cancer
- Investigating the next logical step or continuation of a previous research project
- Proposing work that is an incremental advancement of published data

Optional Nested Teal Postdoctoral Scholar (*NEW for FY13*): A nested Teal Postdoctoral Scholar is being offered as an optional feature of the Pilot Award to foster the next generation of ovarian cancer investigators through mentored research training. Only one postdoctoral fellow (candidate must be named) can be included as a Teal Postdoctoral Scholar within a given applications. Applications that contain a nested Teal Postdoctoral Scholar will qualify for a higher level of funding as described under Section I.D, Funding below. Either the Principal Investigator (PI) or a collaborator on the Pilot Award can be designated as the mentor for the proposed optional, nested Teal Postdoctoral Scholar.

The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

## C. Eligibility Information

- Investigators at the postdoctoral level and above (and equivalent) from academia, research institutions, industry, government agencies, and private foundations are eligible to submit applications.
- For applications with an *optional nested Teal Postdoctoral Scholar*: A nested Teal Postdoctoral Scholar is defined as a postdoctoral fellow who has spent no more than 3 years total in all postdoctoral positions or equivalent.
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

#### D. Funding

- The maximum period of performance is 2 years.
- The maximum allowable direct costs for the entire period of performance are \$225,000 plus indirect costs. If requesting an optional nested Teal Postdoctoral Scholar, the maximum allowable direct costs for the entire period of performance are \$300,000 plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 2 years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Research Supplies
- Equipment
- Research-related subject costs
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings
- Additional travel costs of up to \$1,800 per year for a nested Teal Postdoctoral Scholar to attend ovarian-cancer specific meetings (if applicable)

The CDMRP expects to allot approximately \$6.08M of the \$20.0M FY13 OCRP appropriation to fund approximately 15 Pilot Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.

#### II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<a href="https://cdmrp.org/">https://cdmrp.org/</a>) and (2) application submission through Grants.gov (<a href="https://www.grants.gov/">http://www.grants.gov/</a>).

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

## A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (<a href="http://www.grants.gov/">http://www.grants.gov/</a>) basic search using the Funding Opportunity Number: W81XWH-13-OCRP-PA.

## B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (<a href="https://cdmrp.org/">https://cdmrp.org/</a>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at <a href="help@cdmrp.org">help@cdmrp.org</a> or 301-682-5507.

Pre-applications will be screened based on the merits of the proposed research. Therefore, reviewers will be blinded to the identity of the PI, collaborators, and their organizations(s). *Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or their organization(s) within the Preproposal Narrative is prohibited and will result in administrative rejection of the pre-application and preclude invitation to submit a full application.* In addition, the use of "I," "we," "our," "this organization," or similar wording in phrases that refer to the PI, collaborators, or their organization(s) through the references listed will also result in administrative rejection of the pre-application and preclude invitation to submit a full application.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- Application Information Tab 1
- Application Contacts Tab 2
- Collaborators and Conflicts of Interest (COI) Tab 3

FY13 OCRP Integration Panel (IP) members (<a href="http://cdmrp.army.mil/ocrp/panels/panels13.shtml">http://cdmrp.army.mil/ocrp/panels/panels13.shtml</a>) should not be involved in any preapplication or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at <a href="help@cdmrp.org">help@cdmrp.org</a> or 301-682-5507.

## • Required Files – Tab 4

**Preproposal Narrative (two-page limit):** The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Note: At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.

The Preproposal Narrative should include the following:

- **Research Idea:** State the ideas and reasoning on which the proposed work is based and how the application addresses a central problem in ovarian cancer.
- **Innovation:** Describe how the research is innovative and consistent with the OCRP's definition of innovation.
- **Impact:** Describe the potential short-term and long-term impact of this study on ovarian cancer.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are limited to:

References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). Do not include publication URLs that identify of the PI, collaborators, or their organization(s).

## • Submit Pre-Application – Tab 5

This tab must be completed for the pre-application to be accepted and processed by CDMRP.

#### Other Documents Tab

No additional documents are required.

## **Pre-Application Screening**

## • Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the OCRP, pre-applications will be screened based on the following criteria:

Blinded Content: Identifying or making references to the PI, nested Teal Postdoctoral Scholar (if applicable), collaborators, or their institutions will result in administrative rejection of the pre-application.

- **Research Idea:** How the proposed work addresses a central problem in ovarian cancer.
- o **Innovation:** How the research represents new paradigms, technologies, molecules, or applications that have the potential to prevent ovarian cancer or improve the treatment of individuals with this disease.
- **Impact:** To what degree the proposed study could, whether short-term or long-term, make a significant impact on ovarian cancer.

#### Notification of Pre-Application Screening Results

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application.

The estimated timeframe for notification of invitation to submit an application is indicated on the <u>title page</u> of this Program Announcement/Funding Opportunity.

## C. Application Submission Content and Form

## Applications will not be accepted unless the PI has received notification of invitation.

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<a href="http://www.grants.gov/">http://www.grants.gov/</a>).

**Grants.gov application package components:** For the Pilot Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

**1. SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

#### 2. Attachments Form

• Attachment 1: Project Narrative (six-page limit): Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Reviewers will <u>NOT</u> be blinded to the identity of the PI, nested Teal Postdoctoral Scholar (if applicable), collaborators, and their institutions during the peer and programmatic reviews.

Describe the proposed project in detail using the outline below. The Project Narrative should demonstrate logical reasoning and a sound scientific rationale that is established through a critical review and analysis of the literature. In addition, the Project Narrative should include a description of how the proposed research is innovative as well as its potential impact on ovarian cancer.

- Background: Present the ideas and reasoning behind the proposed research, to include relevant literature citations. *Preliminary data are not required, but are allowed.*
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be attained.
- Specific Aims: Concisely explain the project's specific aims to be supported by this application. If this research project is part of a larger study, present only tasks that this OCRP award would fund.
- Research Strategy: Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail. Address potential problem areas and present alternative methods and approaches. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.
- Attachment 2: Supporting Documentation. Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.

- References Cited: List the references cited (including URLs if available) in the
  project narrative using a standard reference format that includes the full citation
  (i.e., author[s], year published, title of reference, source of reference, volume,
  chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award.
- Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy of each manuscript must be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support (no page limit per letter): Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project.
- Letters of Collaboration (if applicable) (no page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf."
  - o Background: Present the ideas and reasoning behind the proposed work.
  - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
  - o Specific Aims: State the specific aims of the study.
  - Study Design: Describe the study design including appropriate controls.
  - o Innovation: Summarize how the proposed research is innovative and, if proven correct, how it will provide new paradigms, technologies, molecules, or applications that have the potential to prevent ovarian cancer or improve the treatment of individuals with this disease.
  - Impact: Describe how the proposed research is relevant to vision and mission of the OCRP. Outline the potential short-term or long-term impact of the proposed research on ovarian cancer.

• Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf."

The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

Lay abstracts should be written using the outline below:

- Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed work.
  - Do not duplicate the technical abstract.
- Describe the central problem in ovarian cancer addressed in the proposed research.
- Describe how the proposed research is relevant to vision and mission of the OCRP
- Describe the impact that the proposed study could, whether short-term or longterm, have on ovarian cancer.
  - Which individuals will it help, and how will it help them?
  - What are the potential clinical applications, benefits, and risks (potential long-term outcomes)? If the research is too basic for clinical applicability, describe the short-term outcomes.
- Attachment 5: Statement of Work (SOW) (two-page limit): Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.
- Attachment 6: Innovation Statement (one-page limit): Upload as "Innovation.pdf." Summarize how the proposed research is innovative and consistent with the OCRP's definition of innovation.
- Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf." Describe the central problem in ovarian cancer addressed in the proposed research. Describe how the proposed research is relevant to vision and mission of the OCRP. Outline the potential short-term or long-term impact of the proposed research on ovarian cancer.
- Attachment 8: Optional Nested Teal Postdoctoral Scholar Statement (if applicable) (two-page limit): Upload as "ScholarStatement.pdf." The Teal Postdoctoral Scholar Statement must be written by the candidate and should articulate the Scholar's career goals, the proposed training, and how the proposed research training will promote a career in ovarian cancer research. Describe qualifications and achievements that make the postdoctoral fellow the ideal candidate for the Teal Postdoctoral Scholar. The Teal Postdoctoral Scholar's commitment to a career in ovarian cancer research is critical and must be described.
- Attachment 9: Letter of Support for the Teal Postdoctoral Scholar (if applicable) (no page limit): Upload "ScholarSupport.pdf." If a Teal Postdoctoral Scholar is proposed, a letter of support from the mentor should describe not only the

qualifications and achievements that make the postdoctoral fellow an ideal candidate, but should also emphasize the commitment to a career in ovarian cancer research. The letter should include the statement that the candidate meets eligibility requirements.

- 3. Research & Related Senior/Key Person Profile (Expanded): Refer to the General Application Instructions, Section II.C., for detailed information. *Note: Some of the items in this attachment may be made available for programmatic review.* 
  - PI Biographical Sketch (four-page limit): Upload as "Biosketch\_LastName.pdf."
  - PI Past/Current/Pending Support (no page limit): Upload as "Support\_LastName.pdf."
  - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch\_LastName.pdf."
    - Teal Postdoctoral Scholar Biographical Sketch (if applicable).
  - Key Personnel Past/Current/Pending Support (no page limit): Upload as "Support\_LastName.pdf."
- **4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
  - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."
- **5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- **6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

#### D. Submission Dates and Times

All submission dates and times are indicated on the <u>title page</u> of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

#### **E.** Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

#### III. APPLICATION REVIEW INFORMATION

#### A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command, based on technical merit, the relevance to the mission of the DHP and OCRP and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at <a href="http://cdmrp.army.mil/about/fundingprocess.shtml">http://cdmrp.army.mil/about/fundingprocess.shtml</a>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

## **B.** Application Review Criteria

**1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

#### Innovation

- To what extent the proposed research is innovative and consistent with the OCRP's definition of innovation.
- How the proposed research, if proven correct, will provide new paradigms, technologies, molecules, or applications that have the potential to prevent ovarian cancer or improve the treatment of individuals with this disease.
- To what extent the proposed research represents more than an incremental advance of published data.

## Research Strategy and Feasibility

- o To what extent the scientific rationale supports the hypothesis and feasibility of this pilot project, as demonstrated by a review and analysis of the literature.
- How well the hypotheses or objectives, experimental design, methods, and analyses have been developed and how well they support completion of the aims.

- How well the PI identifies potential problems and addresses alternative approaches.
- How preliminary data, if included, support the proposed research.

## Impact

- To what extent the proposed research addresses a central problem in ovarian cancer
- To what extent the proposed research is relevant to vision and mission of the OCRP.
- How well the potential short-term or long-term impact on ovarian cancer is described.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

#### Personnel

- How the research team's background, experience, and expertise are appropriate to execute the proposed work.
- How, if applicable, the nested Teal Postdoctoral Scholar's career goals, future plans, qualifications, achievements, proposed research training, and demonstrated commitment will promote a career in ovarian cancer research.
- To what degree the levels of effort by the PI and other key personnel (including, if applicable, the proposed Teal Postdoctoral Scholar) will ensure success of the proposed work.

#### • Environment

- How the scientific environment is appropriate for the proposed research.
- How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements, if applicable).
- How the quality and extent of institutional support are appropriate for the proposed research.

## Budget

• Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

#### Application Presentation

• To what extent the writing, clarity, and presentation of the application components influenced the review.

- **2. Programmatic Review:** To determine the application's relevance to the mission of the DHP and OCRP, as well as to make funding recommendations, the following criteria are used by programmatic reviewers:
  - a. Ratings and evaluations of the peer reviewers
  - b. Relevance to the mission of the DHP and the OCRP, as evidenced by the following:
    - Relative innovation
    - Relative impact on ovarian cancer
    - Program portfolio balance
    - Adherence to the intent of the award mechanism

## C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

## **D.** Application Review Dates

All application review dates and times are indicated on the <u>title page</u> of this Program Announcement/Funding Opportunity.

## **E.** Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

#### IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from the CDMRP eReceipt System or applications from Grants.gov, the following administrative actions may occur:

## A. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.
- Blinding of pre-application is not followed.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- Submission of an application for which a letter of invitation was not received.

#### B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

#### C. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- A FY13 OCRP IP member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY13 OCRP IP members can be found at <a href="http://cdmrp.army.mil/ocrp/panels/panels13.shtml">http://cdmrp.army.mil/ocrp/panels/panels13.shtml</a>.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research is, or requests funding for, a clinical trial.
- The PI does not meet the eligibility criteria.

#### D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

#### V. AWARD ADMINISTRATION INFORMATION

#### A. Award Notice

Awards will be made no later than September 30, 2014. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

## B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section D, for general information regarding administrative and national policy requirements.

## C. Reporting

Refer to the General Application Instructions, Appendix 4, Section E, for general information on reporting requirements.

#### D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

#### VI. AGENCY CONTACTS

#### A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507 Email: help@cdmrp.org

## **B.** Grants.gov Contact Center

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726

Email: <a href="mailto:support@grants.gov">support@grants.gov</a>

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the application package. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

# VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
Attachments Form	Upload Innovation Statement (Innovation.pdf) as Attachment 6.	
	Upload Impact Statement (Impact.pdf) as Attachment 7.	
	Upload Optional Nested Teal Postdoctoral Scholar Statement (ScholarStatement.pdf), if applicable, as Attachment 8.	
	Upload Letter of Support for the Teal Postdoctoral Scholar (ScholarSupport.pdf), if applicable as Attachment 9.	
	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
December & Deleted	Attach PI Past/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
Research & Related Senior/Key Person Profile (Expanded)	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field (including Teal Postdoctoral Scholar, if applicable).	
	Attach Past/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	